REMARKS

The Official Action dated 14 November 2006 has been carefully reviewed. In view of the amendments submitted herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that the Examiner has deemed the restriction requirement proper and made it final. Applicants continue to respectfully disagree with the Examiner's position in this regard. Applicants wish to clarify that the Examiner in the International Phase of this application found a lack of unity between claims reciting SEQ ID NO: 1 or SEQ ID NO: 3. Claims reading on one sequence or the other were found to be unified before the PCT. Thus, inasmuch as the present claims as amended and as newly presented, all read on SEQ ID NO: 1, which is the unique technical feature linking these claims, Applicants reiterate that the present requirement for restriction is improper and should be withdrawn, or at the very least modified. Additionally, Applicants have elected claims to the isolated peptide product for examination on the merits and request that the Examiner consider rejoining claims 18-21 of the Group III invention, now new claims 68-71 which recite all the features of this product, with the Group I invention, should the product claims ultimately be found in condition for allowance. Moreover, Applicants strenuously disagree with the Examiner's assertion that the bacteriophage encompassed by claim 22 comprises a distinct invention. Clearly a proper search of the Group I invention would reveal art related to bacteriophage expression of this peptide product. Accordingly, it cannot be reasonably be maintained that a search of these Groups of invention, namely Groups V and VII with the Group I claims results in an undue search burden for the Examiner. In light of all the foregoing, Applicants again

request that the Examiner reconsider the restriction requirement issued on July 28, 2006.

The change in the Art unit location for this application is duly noted as is the priority date of December 6, 2002.

At page 2 of the Official Action, the Examiner has objected to claims 3, 12 and 16 as containing a minor informality. The claims have been amended to remove the objectionable subject matter, thereby rendering these objections moot.

Claims 2 and 3 stand rejected under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter. The claims have been amended to include the term "isolated" in keeping with the Examiner's helpful suggestion, thereby obviating this rejection.

The Examiner has rejected claims 3, 12, and 15 under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirements of the statute. Specifically, the Examiner contends that the claims refer to a peptide only by function. The Examiner has also rejected the foregoing claims under the enablement prong of §112, asserting that the specification fails to fully enable the claimed subject matter.

Claims 2, 3, 12, 15 and 16 stand rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. The allegedly ambiguous language has been removed from the claims thereby rendering these grounds of rejection moot.

At page 8 of the Official Action, the Examiner has rejected claims 3, and 12 under 35 U.S.C. §102 asserting that these claims are allegedly anticipated by the disclosure in Kivakumaran et al.

The foregoing constitutes all of the issues raised by the Examiner in the November 14, 2006 Official Action. Applicants

respectfully submit that the claims as presently amended are in condition for allowance. Each of the above-noted objections and rejections under 35 U.S.C. §112, first and second paragraphs, §101 and §102 is, therefore, respectfully traversed.

CLAIMS 3, 12 AND 15, AS AMENDED, SATISFY THE WRITTEN DESCRIPTION REQUIREMENT OF 35 U.S.C. § 112, FIRST PARAGRAPH

It is the Examiner's position that claims 3, 12 and 15 fail to satisfy the written description requirement under 35 U.S.C §112, first paragraph. Specifically, the Examiner asserts that the specification fails to provide an adequate written description to reasonably convey that the Applicants had possession of the invention since only 7 of the amino acids (e.g., SEQ ID NO: 1) are known in the 60 amino acid polypeptide encompassed by the claims and the specific structural features of such polypeptides have not been described. Applicants respectfully disagree.

It is without question that the skilled artisan having the present specification before him would fully appreciate that the present inventors were in possession of the polypeptide encoded by SEQ ID NO: 1 and polypeptides of slightly greater length comprising this sequence. The skilled artisan could readily identify and isolate such slightly elongated sequences based on the enabling disclosure in the present specification given the requirement that the sequences must both possess the "core" sequence of SEQ ID NO: 1 AND bind Nogo, Nogo66 and/or MAG. 60mers or less which do not exhibit this function are outside the scope of the present claims. Furthermore, given the breadth of Applicants disclosure, it would be inequitable to Applicants for the USPTO to insist upon the limitation of the claims to only one sequence. As stated in In re Goffe, 191 USPQ 429 (CCPA 1976):

For all practical purposes, the Board would limit Appellant to claims involving the specific materials disclosed in the examples, so that a competitor seeking to avoid infringing the claims would merely have to follow the disclosure in the subsequently issued patent to find a substitute. However, to provide effective incentives, claims must adequately protect inventors.

The claims now require that the additional sequences possess the reference sequence (SEQ ID NO: 1) provided in the specification and exhibit binding function to proteins which play a role in CNS damage, namely Nogo, Nogo66 and MAG. The Examiner also contends that the claims lack sufficient structural information. Applicants respectfully disagree for the reasons set forth above. Additionally, the Examiner's attention is respectfully drawn to the recent Federal Circuit decision Falkner v. Inglis, where the Court held that "there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure." Falkner v. Inglis, 448 F.3d 1357, 1366 (Fed. Cir. 2006). Thus, the Examiner's requirement appears to be misplaced and contrary to recent case law.

In light of the foregoing remarks and present claim amendments, it cannot be reasonably maintained that the specification does not prove a full written description of the claimed subject matter. Applicants submit that the amended claims and the specification provide sufficient identifying characteristics of the invention to meet the written description requirement under 35 U.S.C. §112, first paragraph. Accordingly, Applicant request that the rejection of the claims on this basis be withdrawn.

CLAIMS 3, 12 AND 15, AS AMENDED, SATISFY THE ENABLEMENT REQUIREMENT OF 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner has rejected claims 3, 12, and 15 for

failing to satisfy the enablement requirement of 35 U.S.C. §112, first paragraph. Specifically, the Examiner asserts that the specification fails to provide guidance for a skilled artisan of how to make and/or use the claimed invention, and that undue experimentation would be required to practice the invention as claimed.

Applicants vigorously dispute the Examiner's contention that practice of the present invention requires undue experimentation. The functional limitations recited in the claims are specific to Applicants invention. The Examiner's attention is respectfully drawn to the Examples which describes the isolation and characterization of peptide sequences which bind the inhibitory domains of the myelin proteins recited in the claims. Methods for assessing the role the peptides play in CNS cells are provided in Aspect I, Examples 4, 5 and 6. These methods facilitate the identification and characterization of peptides encompassed by the present claims.

The Examiner has offered no well founded reasons for doubting that the peptides would not work as suggested if additional amino acids are present. In support of her position, the Examiner applied the enablement factors provided at §2164.01(a) of the MPEP and concluded that, in view of the allegedly undeveloped and unpredictable state of the art and the alleged absence of guidance with regard to which amino acids to add, a skilled artisan would have to perform undue experimentation to practice the full scope of the claimed invention.

Applicants respectfully disagree with the Examiner's position. In In re Wands, 8 USPQ2d 1400 (1988), the Federal Circuit Court of Appeals held that engaging in experimentation to practice a claimed invention does not render the disclosure non-enabling as long as the experimentation required is not "undue". The Court stated that: "The determination of what

constitutes undue experimentation in a given case requires the application of a standard of reasonableness . . . The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In the present case, the experimentation necessary is merely routine and is inherent in the nature of the art. Therefore, there is no undue burden of experimentation. The level of skill in the art of molecular biology and the creation of myelin binding proteins or peptides is quite high, and the required techniques are familiar to those skilled in this art area. Additionally, the description of techniques for identifying and obtaining the peptides of the invention occupies a large part of the application as discussed above.

The Examiner's attention is also respectfully drawn to In re Angstadt and Griffin, 190 USPQ 214 (CCPA 1976) wherein the Court held that an applicant need not demonstrate the operability of each and every species covered by a claim and that patentable claims may cover inoperable species. In the present situation, the skilled artisan knows how to ensure successful operation of the claimed invention and can readily find embodiments in which peptides will function as claimed, so that occasional failure of a peptide to bind an inhibitory domain of a myelin protein with the desired characteristics does not mean that the claim as a whole has not been enabled.

To gain reasonable protection for the invention, the Applicants should be allowed claims that cover the disclosed sequence plus similar variants. Notably, several variants are disclosed in the present application. It is well known that conservative substitutions can be made in a protein by changing the nucleic acids so that a different but similar

amino acid is inserted into the polypeptide sequence. Frequently, a point mutation has no significant effect on function. Therefore, the skilled artisan can readily envisage variants of the sequences provided that would be fully functional but would have a slightly different sequence to the one disclosed in the application. Applicants should reasonably be allowed to protect such simple sequence variants.

Lastly, Pfaff v. Wells Elecs., made it clear that although "reduction to practice ordinarily provides the best evidence that an invention is complete . . . it does not follow that proof of reduction to practice is necessary in every case." 525 U.S. 55 at 66 (1998).

In light of all the foregoing, Applicants submit that the present claims are enabled. Accordingly, the rejection of the claims under §112, first paragraph for inadequate enablement is untenable and should be withdrawn.

THE CLAIMS AS AMENDED ARE NOVEL OVER SIVAKUMARAN ET AL.

In order to constitute evidence of lack of novelty under 35 U.S.C. §102(b), a prior art reference must identically disclose each and every element of the rejected claim. In re Bond, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). Each of the claims as amended or newly presented require the presence of the "core" sequence of SEQ ID NO: 1 which is YLTQPQS. The sequence disclosed in EMBL Acc. No. Q9BDQ2, namely, tceliyltqp sss lacks the second Q in Applicants SEQ ID NO: 1. Accordingly, Applicants claims are not anticipated by this disclosure as the sequences described by the cited reference and encompassed by the present claims differ. Accordingly the rejection of claims 3 and 12 based on this reference is improper and should be withdrawn.

Favorable consideration leading to prompt allowance of

the present application is respectfully requested.

Respectfully submitted,
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